EXHIBIT 3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Tutino *et al.*	Confirmation No.: 6628
Application No.: 12/783,390	Group Art Unit: 1617
Filed: May 19, 2010	Examiner: Pipic, Alma
For: Formulations of 4-Amino-2-(2,6-Dioxopiperidine-3-yl)isoindoline-1,3-dione	Attorney Docket No.: 9516-831-999 (CAM No.: 501872-999831)

DECLARATION BY ANTHONY TUTINO

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Anthony Tutino, declare and state that:

1. I received my Bachelor of Science degree in Pharmaceutical Sciences from Saint John's University, New York. I hold licenses in the practice of Pharmacy from New York and New Jersey. I also received a Certification in Project Management from The George Washington University, Washington, D.C.

2. From 1984 to 1996, I was with Sandoz Pharmaceuticals, lastly as the Associate Director of Technology Development. From 1997 to 2004, I was a Director of Process Development at Novartis Pharmaceutical. From 2004 to present, I have been with Celgene Corporation, Summit, NJ, the assignee of the current application, currently as the Executive Director of Global Pharmaceutical Development and Technology. I am a named inventor of the above-identified application.

3. I am familiar with the disclosure and claims of the current patent application. I understand that the pending claims recite, *inter alia*, pharmaceutical compositions of pomalidomide consisting of specific amounts of pomalidomide and specific amounts of pregelatinized starch, sodium stearyl fumarate and spray dried mannitol. I have reviewed the Office Action and references cited in the Office Action.

4. I understand that one of the issues is whether it would have been plausible for one skilled in the art to pick the particular excipients recited by the current claims from the list of excipients provided in U.S. Publication No. 2007/0155791 by Zeldis *et al.* ("Zeldis"). It is my opinion that one would not have been able to arrive at the dosage forms recited by the current claims based simply on the references cited in the Office Action for at least the following reasons.

5. In developing pharmaceutical formulations, a common practice is to start with 1:1 compatibility tests between active pharmaceutical ingredient ("API") and various commonly used excipients. In short, the 1:1 compatibility test involves combining the active ingredient with an excipient in a ratio that would normally be found in a formulated dosage product. These mixtures are then placed at stress conditions (high temperature and high humidity) and tested at regular intervals to determine if any degradation of the active ingredient is taking place. The test is designed to provide insight as to whether an excipient would be compatible with the API being formulated, and as such, once certain excipients are found compatible with API from the tests, it is expected that a formulation using those excipients would not present a compatibility problem.

6. Thus, in developing the pomalidomide formulations, 1:1 compatibility tests have been conducted between pomalidomide and various candidate excipients. The tested excipients included anhydrous dibasic calcium phosphate, lactose anhydrous, corn starch, pregelatinized starch, microcrystalline cellulose, spray dried mannitol, croscarmellose sodium, sodium starch glycolate, sodium starch fumarate, and magnesium stearate. From the testing, it was found that pomalidomide is compatible with each of those excipients tested.

7. Based on that result, various test formulations were made using the excipients that were found to be compatible with pomalidomide. The components of the tests formulations are shown below:

Ingredient	Function	Formulation (Quantity per blend, %)									
		A	B	C	D	E	F	G	H	I	J
CC-4047 (Process B)	Active ingredient	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40
Anhydrous dibasic calcium phosphate	Bulking agent	45.35		95.35	45.35	45.35		45.35	45.35	45.35	
Spray dried mannitol	Bulking agent						45.35				
Pregelatinized starch	Bulking agent	50.00	95.35		54.00	50.25	50.00		50.00	50.00	
Starch (corn starch and pregelatinized)	Bulking agent							50.00			
Lactose anhydrous	Bulking agent										75.00
Microcrystalline cellulose	Bulking agent										20.60
Croscarmellose sodium	Disintegrant	4.00	4.00	4.00		4.00	4.00	4.00		4.00	4.00
Sodium starch glycolate	Disintegrant								4.00		
Sodium stearyl fumarate	Lubricant	0.25	0.25	0.25	0.25		0.25	0.25	0.25		
Magnesium stearate	Lubricant									0.25	1.00

8. To my surprise, it was found that Formulations A, C, E, G, H and I above were found to present a compatibility problem, *i.e.*, were unstable after two weeks storage. This was unexpected because I would have expected that compatibility issues would not exist based on the 1:1 compatibility tests preliminarily conducted for each of the excipients contained in those formulations. Consequently, it is my opinion that one reading Zeldis could not have just picked and chosen random excipients from the list of excipients provided in that reference and arrive at a formulation that does not exhibit this compatibility problem.

9. Next, Formulations D, F and J, which did not have the compatibility issues, were further advanced for testing on long term stability. After six months of storage at the accelerated condition (40°C/75% RH) and 12 months at the ambient condition (25°C/60% RH), the formulations were tested for relative impurity levels. The results were as follows:

Timepoint			T0	1 month	3 months	6 months			9 months	12 months
Conditions °C/%RH				40/75	25/60	40/75	25/60	40/75	25/60	25/60
Strength (mg)	Formulation	Impurity	Relative Impurity (%)							
1	D	Impurity A	0.02	0.27	0.14	0.46	X	X	X	X
		Impurity B	0.00	0.04	0.02	0.13	X	X	X	X
	F	Impurity A	0.01	0.00	0.00	0.01	0.03	0.05	0.01	0.01
		Impurity B	0.00	0.01	0.00	0.00	0.01	0.02	0.00	0.00
	J	Impurity A	0.55	0.15	0.44	0.64	X	X	X	X
		Impurity B	0.00	0.01	0.00	0.00	X	X	X	X
5	D	Impurity A	0.02	0.19	0.09	0.32	X	X	X	X
		Impurity B	0.00	0.07	0.02	0.12	X	X	X	X
	F	Impurity A	0.01	0.00	0.00	0.01	0.00	0.01	0.01	0.00
		Impurity B	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.00

10. In the table above, the denotation "X" indicates that no further study was conducted to the batch beyond the specified period due to high level of impurities. As can be seen from the above, only Formulation F, *i.e.*, formulation claimed in this application, was shown to be stable beyond 3 months period. It is my opinion that this further shows that it would have been impossible for one reading Zeldis and other references cited in the Office Action would arrive at the currently claimed dosage forms without specifically knowing that the particular combination of the particular excipients recited by the current claims would provide a formulation having favorable compatibility and stability properties.

11. With regard to the prophetic formulation described in Example 8 of the Zeldis, it is my opinion that the formulation, even if actually made, would not possess the advantageous stability profile possessed by the currently claimed dosage forms. This is because Formulation J, a candidate formulation tested during the development of the current dosage forms, which contained a significant amount of microcrystalline cellulose, did not have the advantageous stability exhibited by the currently claimed dosage forms. (*See* Table above, Formulation F in comparison with Formulation J).

12. The degradation of pomalidomide is caused by hydrolysis. In Formulation J, none of the excipients, other than microcrystalline cellulose, contained available, unbound water. Therefore, the stability issue observed in that formulation was attributed to the presence of microcrystalline cellulose, which has a loss on drying (LOD – measure of water content) of approximately 5%. As the formulation provided in Example 8 of Zeldis also contains a significant amount of microcrystalline cellulose (and thus, water), I would expect that the Zeldis formulation would exhibit an unfavorable stability issue similar to that exhibited by Formulation J.

13. I, Anthony Tutino, declare that all statements made herein are of my own knowledge to be true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent that may issue there from.

Dated: 14 June 2013

Anthony Tutino

ANTHONY TUTINO, R.Ph.